

### **REMARKS**

This amendment responds to the Office Action dated November 27, 2007. Claims 1, 2, 4-6, 44-51, 62, 63, and 65 are in the application. Claims 1, 44, and 62 are in independent form. Claims 3 and 64 are cancelled by this amendment.

Reconsideration is respectfully requested in light of the following remarks.

### **35 USC § 103**

The claims stand rejected under 35 USC § 103 for obviousness over U.S. Pat. No. 6,611,806 to Harvey ("Harvey") in view of U.S. Pat. No. 5,771,657 to Lasher ("Lasher") and U.S. Pat. No. 6,464,142 to Denenberg. Applicants respond as follows.

Harvey is directed to a computer system for tracking the lot numbers of pharmaceuticals that are administered to patients. The system includes a plurality of remote systems, each typically at a different hospital. Each remote system associates the lot numbers of pharmaceuticals that are administered to patients. As described by Harvey, there is great value in being able to quickly and efficiently track the patients to whom pharmaceuticals, such as blood derivatives, have been administered. One example is product recall. Occasionally, a pharmaceutical will be recalled by its manufacturer or by the FDA. The ability to track pharmaceuticals to patients is also of great importance to research. Fast and efficient tracking can facilitate the evaluation of drug effectiveness.

Lasher is directed to an automated prescription dispensing and packing system, empty prescription bottles are labeled and loaded in assigned locations in carriers. Pills are automatically dispensed into the prescription bottles in the carriers. Ranks of carriers containing filled prescription bottles are assembled at stations where the bottles are unloaded and packed into shipping containers with literature printed by the system. Multiple bottles of an order are automatically packed in the same shipping container. As noted by the Examiner, Lasher describes an implementation in which some or all of the bottles in an order are packed manually.

Denenberg is directed to a will call system for managing just the storage and removal of filled prescriptions. In the Denenberg will call system, however, the breaking a

light beam by a pharmacy worker in a will-call storage system functions as a proxy for actually detecting the presence of a specific filled prescription stored therein. Dannenberg provides no teaching or suggestion relating to detecting or tracking the position of prescriptions upstream of the will call storage area.

Independent claims 1 and 62 have been amended to include the subject matter of respective claims 3 and 64, which have been cancelled. Independent claims 1 and 62 further recite that prescription orders are moved by hand to a second location within the pharmacy for manual filling upstream of the storage area, thereby clarifying that the filling of prescriptions is preformed manually at the second location. Claim 44 has also been amended to recite manual filling of the prescription.

With respect to claim 1, the Examiner states that Harvey discloses the claimed subject matter, including a machine-readable tag operably secured to each prescription order. (Citing Harvey, col. 4, lines 16-56.) The Examiner notes that Harvey does not disclose the method of moving each of the prescription orders by hand to a filled prescription order compartment having a corresponding compartment tag reader. The Examiner cites Lasher as teaching the moving by hand of each prescription order to a filled prescription compartment having a corresponding compartment tag reader. (Citing Lasher, col. 13, lines 19-47 and col. 15, lines 1-15.) Noting that neither Harvey nor Lasher discloses moving prescriptions between spaced apart locations by hand, the Examiner cites Denenberg at col. 10, lines 19-36. With regard to claim 3, the Examiner states that Lasher discloses "moving prescription orders by hand to a second location upstream of the storage area" and automatically detecting the presence of the prescription orders at the second location regardless of the orientation of the tags. (Citing Lasher, col. 3, lines 31-67 and col. 5, lines 13-37.) Applicants respond as follows.

The Examiner notes that nonobviousness cannot be shown merely by attacking the individual references. However, even a rejection for obviousness the Examiner must show in the cited art a teaching or suggestion for each and every feature recited in the claims. Moreover, the Examiner must also take each reference for its teaching as a whole and cannot pick and chose individual features from a reference absent its teaching as a whole.

Applicants submit that the rejection and should be withdrawn because the rejections of the independent claims fail to show in the cited art a teaching or suggestion for each and every feature recited in the claims. With regard to claim 1, the Examiner cites Harvey, col. 4, lines 16-56, as disclosing a machine-readable tag being operably secured to each prescription order. The cited passage is reproduced below:

A key feature of the present invention is to record an association between each prescription issued by the physician which is to be tracked and the lot number or numbers of the pharmaceuticals that are actually administered to the patient in fulfillment of the prescription. Although referring to the information that identifies a particular pharmaceutical as a lot number, it is to be understood that the phrase "lot number" is intended to connote any type of information that is used to identify the pharmaceutical, whether it is called a "lot number" or not. This includes information that identifies a particular batch or set of products that is administered to a patient, or any other type of organizational arrangement.

The initial associations are typically made through the use of one or more remote stations, such as the remote stations 11 and 13 shown in FIG. 1.

The next step is for the prescription to be received by a remote station, such as the remote station 11 in FIG. 1, as illustrated by a Received Prescription block 17 in FIG. 2.

The invention embraces a broad variety of mechanisms for accomplishing this result.

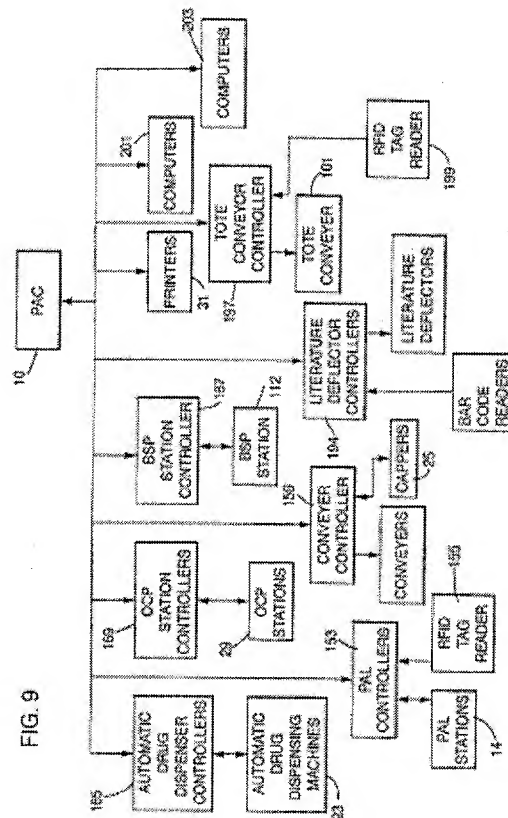
In one embodiment, the remote station 11 is used by the pharmacist. If the prescription is received by the pharmacist on a piece of paper, the pharmacist enters the details of the prescription in the station 11 under the control of a data entry program 19 that is controlling the operation of the station 11. The fields of information that are entered can vary widely. Typically, they will include information relating to the patient, the patient's physician, the prescribed pharmaceutical, the quantity ordered and the prescription number.

In an alternate embodiment of the invention, the prescription information is entered at another station (not shown in the figures) and is delivered over a computer network to the pharmacist at the station 11 for further processing.

In either case, the next step in accordance with one embodiment of the present invention is to determine whether the prescription is directed to one of the pharmaceuticals that should be tracked by the present invention, as reflected by a Track? block 21 in FIG. 2. (Harvey, col. 4, lines 16-56.)

This passage describes two embodiments for entering prescription information. Either a pharmacist enters the details of the prescription from a piece of paper at station 11, or the information is entered at another station. Nothing in this described manual entry of information corresponds to the claimed separate machine-readable tag operably secured to each prescription order upstream of said storage area, each said tag having a unique identifier that is readable by a tag reader in proximity to the tag regardless of its orientation relative to the tag reader.

Moreover, in response to applicants' prior argument that Harvey does not teach machine readable tags being secured to prescription orders, the Examiner cited Lasher, Fig. 9, col. 13, lines 50-67, col. 14, line 14, and col. 15, lines 51-67. Applicants reproduce below a copy of Fig. 9 of Lasher.



As described at col. 3, lines 27-28, Fig. 9 illustrates “the architecture of the computer system used in the system of the present invention.” Fig. 9 does not show prescription orders or machine readable tags that are secured to prescription orders. Likewise, the passage of Lasher cited by the Examiner (reproduced below) make no mention of machine readable tags that are secured to prescription orders.

As shown in FIG. 9, PAC 10 controls the components of the system through a distributed logic system. PAC 10 receives the prescriptions from the host computer and stores the prescriptions in the order file. PAC 10 controls the PAL stations 14 via controllers 153. PAC 10 makes a batch file for each carrier containing the prescription information for each prescription to be loaded into the corresponding carrier and the exact locations in the carrier where the prescription bottles of the prescriptions are to be placed. These batch files are transmitted to the controller 153 which controls label printers of the PAL stations 14 to print the bottle prescription labels, label the bottles, and control the PAL stations to load the labeled bottles in the scheduled locations in a carrier. Transducers 155 read the carrier identification from the RFID tag when a carrier has been loaded at a PAL station and the loaded carrier is dispatched to an automatic drug dispensing machine and controllers 153 transmit the carrier identification to PAC 10. PAC 10 stores the carrier identifications of the carriers in association with the scheduled locations for the prescription bottles loaded in these carriers and with the corresponding orders so that for each order, PAC can retrieve the carrier identifications and the

scheduled locations in the carriers of the prescription bottles for the order.

The conveyer system is controlled by PAC 10 via carrier conveyer controller 159. When the PAL stations have completed loading of the orders in the batch file into a rank of carriers, PAC 10 issues a move instruction to the conveyer controller 159 to cause the conveyers 45 to transport the rank of carriers now filled with labeled empty prescription bottles to the automatic drug dispensing machines 23. The controller 159 also controls the cappers 25.  
(Col. 13, line 50 - col. 14, line 14.)

PAC 10 also interfaces with computers 201 at the quality assurance area 109 and with computers 203 at the package quality assurance area 96. The computers 201 and 203 provide information to pharmacists or technicians about the orders and prescriptions in the packages and prescription bottles received at these quality assurance areas.

The above-described system automatically dispenses tablets and capsules into prescription bottles, assembles the prescription bottles for a common order into shipping containers, prints literature packs for each order and automatically inserts the literature packs into the shipping containers and prints the mailing labels on the shipping containers so that upon completion of the automatically operated system the order is ready to be mailed.

The above automatic system is accomplished with a very high throughput of orders and, at the same time, provides for checks and balances to make sure that the system is operating properly and provides for automatically diverting orders and bottles for manual inspection for problems in the automatic system that have been detected.  
col. 15, line 51- col. 16, line 3.)

The specification passages of Lasher cited by the Examiner do not teach or suggest machine readable tags being secured to prescription orders. Rather, Lasher is directed to applying a machine readable tag to each carrier within which 24 separate prescription are carried:

Transducers 155 read the carrier identification from the RFID tag when a carrier has been loaded at a PAL station and the loaded carrier is dispatched to an automatic drug dispensing machine and controllers 153 transmit the carrier identification to PAC 10. PAC 10 stores the carrier identifications of the carriers in association with the scheduled locations for the prescription bottles loaded in these carriers

The application of tags to carriers of prescription bottles, rather than to prescription orders as recited in the claims, is further clarified in the description of Lasher Figs. 4A and 4B:

As shown in FIGS. 4a and 4b, a bottle carrier has 24 wells 44 to receive bottles which are arranged in a 4.times.6 array. The leading row which consists of four wells are sized to accommodate the large sized bottles and the remaining five rows are sized to receive the small bottles. This breakdown is a close approximation to the anticipated requirements for large and small bottles. The bottles all have the same diameter, as do the wells, but the wells in the first four rows are deeper to accommodate the larger bottles which have a greater axial dimension. The well bottoms in the carriers are positioned so that the tops of the bottles loaded in the carriers are all at the same level.

The bottle carrier is also provided with an RFID tag 46 which uniquely identifies the carrier. The carrier identification can be read out from the RFID tag by radio frequency transducers. The RFID tags and transducers are available from Data Logic Company. After a carrier is loaded at a PAL station, the RFID tag on the carrier is read and stored by PAC 10 in the order file associated with the prescription orders of bottles loaded on the carrier.

Each bottle becomes unique when the label is applied to the bottle, and it must be placed at a

predetermined scheduled position within the bottle carrier by a PAL station 14. It is critical that no deviation occur between the logical position of the bottle determined by PAC and the physical location of the bottle on the carrier.

Lasher describes applying machine readable tags to carrier trays in which a machine carries 24 separate prescription bottles. Lasher does not apply a separate tag to each prescription order, as recited in the independent claims. Moreover, Lasher is specifically directed to an automated machine for handling prescriptions and does not teach or suggest prescription orders being moved by hand, as recited in the claims.

The use of separate tags for separate prescription orders, as recited in claim 1, provides physical tracking of individual prescription orders in a pharmacy where the prescription orders are moved by hand, thereby providing reliable location tracking of each individual prescription order. In contrast, Lasher employs only one tag per 24 prescription bottles because Lasher is directed to a fully automated handling system. Lasher teaches away from moving prescription bottles by hand and rather is directed to a fully-automated system that is directed to mail-order pharmaceutical suppliers:

The use of mail service to fill prescriptions has been highly successful in lowering the costs of providing drugs to consumers. The filling of prescriptions and mailing the filled prescriptions to consumers is labor intensive and a pharmacy can significantly reduce its costs, improve quality, and reduce turn around time by automating the prescription filling and assembling procedures. (Lasher, col. 1, lines 11-17.)

Such large-scale automated machines are too bulky and expensive for most retail pharmacies and are unrelated to the operation of such pharmacies. Applicants submit, therefore, that the Lasher reference specifically relied upon by the Examiner to teach operably securing machine readable tags to prescription orders provides no mention of applying a separate tag to each order to accommodate that moving or prescription orders by hand, as recited in the independent claims. Applicants submit that, therefore, the rejections of the independent are improper and should be withdrawn for failure to identify in the prior art the machine readable tags recited in the claims.

Moreover, Lasher is directed to a fully automated prescription dispensing and packing system. Such fully automated systems are incompatible with many pharmacy operations, as described in the application at page 4, lines 1-15:

Similarly, some pharmacy vendors have attempted to automate the

prescription filling aspect of a pharmacy by incorporating an automatic assembly line process for filling prescription orders. In particular, an operator enters a prescription order into a computer system, which causes a conveyor-type system to deliver an empty vial to an automated drug dispenser. The filled vial is then automatically matched with a label and presented to a pharmacist for final review and approval. While these types of devices facilitate the quick and efficient filling of prescription orders, they are expensive for use in a retail pharmacy environment, and they occupy a large amount of limited space within the pharmacy. Moreover, they still require pharmacy workers to perform manual tasks such as verifying insurance and renewability of the prescription, and processing the various forms of prescription orders before and after they are entered into the automated system. Accordingly, they do not permit the easy tracking of prescription orders as they travel within the automated pharmacy environment.

The independent claims each recites manually filling prescription orders and moving prescription orders by hand to one of the compartments in an array of compartments as a filled prescription order. As amended, the independent claims also recite moving prescription orders by hand to a second location within the pharmacy upstream of the storage area for manual filling of the prescription, the second location having a second location tag reader in communication with the computer system.


Lasher is directed to a fully automated system that makes no provision for movement of prescription orders by hand. As noted by the Examiner, Lasher does accommodate manual handling of exception prescriptions (e.g., narcotics or controlled substances). However, Lasher provides no teaching or suggestion of detecting the locations of individual prescription orders, whether at a storage area or at a second location upstream of the storage area, particularly orders that are being handled manually. Lasher is directed only to the automated system tracking of prescription bottle carriers with a fixed set of prescription bottles. The manual handling of prescriptions by Lasher is outside such automated tracking. Indeed, the absence of such tracking of individual, manual prescriptions by Lasher is the very problem resolved by the claimed invention in the present application. Applicants submit, therefore, that the cited references as a whole fail to teach or suggest the subject matter of independent claims 1, 44, or 62, or their respective dependent claims.

## CONCLUSION

In view of the foregoing, applicants submit that all of the currently pending claims are in condition for allowance, and respectfully request that the case be passed to issuance. If the Examiner has any questions, he is invited to contact applicants' attorney at the below-listed telephone number.

May 27, 2008

Respectfully submitted,

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